

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE)
LITIGATION)
_____)

THIS DOCUMENT RELATES TO:)

*United States of America ex rel. Ven-a-
Care of the Florida Keys, Inc. v. Abbott
Laboratories, Inc.*, Civil Action No. 06-
11337-PBS;)

MDL No. 1456

Civil Action No. 01-12257-MBB

Hon. Marianne B. Bowler

*United States of America ex rel. Ven-a-
Care of the Florida Keys, Inc. v. Dey, Inc.,
et al.*, Civil Action No. 05-11084-PBS; and)

*United States of America ex rel. Ven-a-
Care of the Florida Keys, Inc. v.
Boehringer Ingelheim Corp., et al.*, Civil
Action No. 07-10248-PBS)

UNITED STATES' RESPONSE TO PROCEDURAL ORDER RE: RECUSAL

The United States of America ("United States") respectfully submits this response to the Procedural Order Re: Recusal (Docket # 5252) ("Procedural Order"). While the United States does not have sufficient facts to take any position, it hereby provides additional information that may inform the Court's decision whether recusal is appropriate.

The Procedural Order indicates that Dr. Pfeffer holds one or more patents with active licensing agreements with Boehringer Ingelheim International GmbH ("BI International"). The United States understands this could mean that Dr. Pfeffer holds a

patent on a pharmaceutical product, that he has a licensing agreement with BI International that authorizes BI International to manufacture and sell the product, and that under the agreement Dr. Pfeffer receives some portion of the profits. If that is the case, there may be a relevant question whether Dr. Pfeffer's financial interest under such a licensing agreement "could be substantially affected by the outcome of the proceeding." 28 U.S.C. § 455(b).

The United States has sued several Boehringer Ingelheim affiliates,¹ but has not sued BI International. The companies sued by the United States are first- or second-line U.S. subsidiaries of the German company Boehringer Ingelheim Auslandsbeteiligungs GmbH ("BIA"). BIA is a wholly-owned subsidiary of BI International.² The United States has reason to believe that BI International holds the licensing rights for many products manufactured and sold by other Boehringer Ingelheim companies.

The United States does not know whether the product on which Dr. Pfeffer has a licensing agreement with BI International is manufactured or sold by any of the U.S. defendants sued by the United States, or, if so, whether those U.S. sales represent a significant percentage of total world-wide sales. The United States does believe a judgment against the Boehringer Ingelheim defendants in this suit could be substantial,

¹ The United States has sued Roxane Laboratories, Inc., n/k/a Boehringer Ingelheim Roxane, Inc.; Roxane Laboratories, Inc.; Boehringer Ingelheim Corporation ; and Boehringer Ingelheim Pharmaceuticals, Inc.

² The organization of the family of Boehringer Ingelheim companies is complex and frequently changing.

although expert reports on damages have not yet been disclosed. Absent more information, the United States does not have a position concerning whether a judgment in this case could have a significant impact on Dr. Pfeffer's income from the licensed product.

Respectfully Submitted,

For the United States of America,

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May 12, 2008

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "UNITED STATES' RESPONSE TO PROCEDURAL ORDER RE: RECUSAL" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: May 12, 2008

/s/ George B. Henderson, II